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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,356	06/25/2001	Thomas Mathew Cocks	DAVI122.001A	7835

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EXAMINER

LANDSMAN, ROBERT S

ART UNIT PAPER NUMBER

1647

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,356

Applicant(s)

COCKS ET AL.

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-9,20-22 and 24-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5-9, 20-22 and 24-32 is/are rejected.
- 7) ☒ Claim(s) 1, 2, 5-9, 24, 26-32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/26/05 has been entered.

1. Formal Matters

- A. The Amendment dated 6/20/05 has been entered into the record.
- B. The Amendment dated 5/26/05 has been entered into the record.
- C. Claims 1, 2, 5-9, 20-22 are pending. New claims 24-32 have been added. Therefore, claims 1, 2, 5-9, 20-22 and 24-32 are
- D. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Specification

- A. All objections to the specification have been overcome in view of Applicants' amendment to the Brief Description of Figures.

3. Claim Objections

- A. The objection to the claims regarding "one or more amino acids" has been withdrawn in view of Applicants' amendment to the claims.
- B. The syntax of claims ^{and 24} 1 could be improved. The phrase "said method comprising administering to said animal, an effective amount for mediating relaxation of said airway of a peptide" could be improved by rewording the claim, for example, as "...said animal an amount of a peptide effective for mediating..."

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6.29.05

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C. Claim 31 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of previous claim 24. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 31 recites replacing a natural amino acid with a non-natural amino acid. However, this limitation is found in claim 24.

4. Claim Rejections - 35 USC § 112, second paragraph

A. All rejections under 35 USC 112, second paragraph, have been withdrawn in view of Applicants' amendments to the claims.

5. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

A. The rejection of all claims under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' amendments to the claims to limit the number and types of substitutions to SLIGRL, including "derivatives" and substituting every amino acid.

B. Claim 2 remains rejected and new claim 25 is also rejected under 35 USC 112, first paragraph, for the reasons already of record on page 4 of the Office Action mailed 12/28/04. Applicants argue that the Declaration by Mr. Cocks, as well as the references submitted in the Response dated 10/4/04 demonstrate that A549 cells are an art-accepted model for the studying and predicting the effect of compounds in humans. This argument has been considered, but is not deemed persuasive. While Mr. Cocks does discuss that he and other colleagues do use A549 cells, there is no discussion that this is an art-accepted model for extrapolation to humans. This information also cannot be found in the references. Applicants are urged to point out which references, and where in these references, support for the use of A549 cells as a human model of disease study can be found.

6. Claim Rejections - 35 USC § 112, first paragraph – written description

A. The rejection of all claims under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' amendments to the claims to limit the number and types of substitutions to SLIGRL, including "derivatives" and substituting every amino acid.

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7. Claim Rejections - 35 USC § 112, first paragraph – new matter

A. The rejection of claims 1, 2, 5-9, 20 and 21 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' amendments to the claims to limit the number of amino substitutions to SLIGRL as one.

8. Claim Rejections - 35 USC § 102

A. Claim 20 is rejected under 35 U.S.C. 102(e) as being anticipated by Costanzo (U.S. Patent No. 6,323,219). The claim recites a method of screening for agents for treatment or prophylaxis of airway inflammation by screening for PAR2 activators. Costanzo teaches that SLIGRL is a PAR2 activator (column 2, lines 19-30) and also teaches the screening of PAR2 receptors for ligands which activate the receptor (Figures 1-4). Though Costanzo does not specifically teach that these activators are capable of treating airway inflammation, the limitations of the claim is still met. The instant process claims would inherently be identical regardless of any knowledge of the intended use of the identified compounds (Ex parte Novitski, 26 USPQ 1391).

9. Claim Rejections - 35 USC § 103

A. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Costanzo (U.S. Patent 6,323,219) in view of Applicants' specification. The claims recite substituting SLIGRL with a non-natural amino acid. The teachings of Costanzo are seen in the above rejection under 35 USC 102. Costanzo does not teach amino acid substitutions. However, page 17, line 19 to page 23, line 21, of Applicants' specification do teach making non-natural substitutions. It is well-known in the art, as seen in the present specification, that non-natural amino acids are important to stabilize compounds (page 23, lines 19-21). It would have been obvious to the artisan at the time of the present invention to have used modified amino acids in order to increase the half-life of the peptides for therapeutic or other purposes.

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10. Art of Interest

A. No rejection of claims 1, 2, 5-9, 21-22 or 24-32 is being made over Costanzo (U.S. Patent No. 6,323,219). Costanzo teaches that PAR2 receptors are activated by SLIGRL (column 2, lines 19-30). Costanzo also teaches inhibitors of PAR can be used to treat asthma (column 31, lines 24-60, especially line 38) and that these compounds can be modified to penetrate the skin (column 9, lines 1-9). However, the Examiner could not make a prima facie case that SLIGRL, a PAR2 activator, would mediate airway relaxation.

11. Conclusion

A. Claims 1, 5-9, 24 and 26-32 would be allowable if the claim objections were overcome.


Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on M-Th 10 AM – 7 PM (eastern); alt F 10 AM – 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert Landsman
Primary Examiner
Art Unit 1647


ROBERT S. LANDSMAN, PH.D.
PRIMARY EXAMINER